JLI Meeting 7/3/02

→ Chesapeake IRB:
- start screening as soon as IRB approval
- post-pone start till mid/end October
- complete by mid-November (11/11)

CRFs entered 4 weeks after clinical finalized

tuesday noon Submission
fall for following wednesday review
2-3 business days later for response
* 8/12-13 – best case scenario for receipt of IRB feedback

(tent.)-10:00 am t/c w/ PAREXEL (confirm end of this week)
? how long does MDS require for analysis/generation of draft report

Revised protocol + IC → this week by so prepared to submit
↳ Chesapeake
↓
Ortrun
↳ MDS change protocol
Chesapeake IRB info (Ortrun)

Institutional IRB (MedStar) declined to review protocol

Preparing for submission to Commercial IRB (calling back this afternoon with details)

Best case: put together submission for review on 8/7 (expect feedback by 8/14)

* Revision to protocol (to MedStar ref)
* poss. " IC (MedStar context)
↳ may require new IC from/at

PM3006788024

Source: https://www.industrydocuments.ucsf.edu/docs/ykmx0001